Remarks

Claims 133-146 are pending in the subject application. By this Amendment, Applicants have amended claim 134. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 133-146 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 133, 134, and 136-138 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. The Office Action argues that these claims introduce new matter into the subject application as the fragment of SEQ ID NO: 5 spanning amino acids 1-1629 was not disclosed in the as-filed specification. Applicants respectfully traverse and assert that a fragment comprising a "contiguous span of at least 6 amino acids, preferably at least 8 or 10 amino acids, more preferably at least 12, 15, 20, 25, 30, 40, 50, or 100 amino acids of SEQ ID No 5, wherein said contiguous span includes at least 1, 2, 3, 5 or 10 of the amino acid positions 1 to 1629 of the SEQ ID No 5" is discussed at page 49, lines 15-29, of the as-filed specification. Further, original claim 46 presents such language as well. Applicants respectfully submit that this language conveys to one of ordinary skill in the art that a fragment of SEQ ID NO: 5 comprising amino acids 1-1629 was specifically described in the as-filed specification. Particularly, it is respectfully submitted that one skilled in the art would have recognized that amino acids 1 to 1629 of SEQ ID NO: 5 was a contiguous span of at least six amino acids that included at least 1, 2, 3, 4 or 10 of the amino acid positions 1 to 1629. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim 134 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully assert that the claims as filed are definite. However, in order to lend greater clarity to the claimed subject matter, Applicants have amended the claim. Specifically, Applicants have amended claim 134 to indicate that the polypeptide is associated with prostate cancer. Accordingly,

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reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 133-138 are rejected under 35 U.S.C. § 101 as lacking a specific and/or substantial utility or a well established utility. In addition, the claims are rejected under 35 U.S.C. § 112, first paragraph, as nonenabled on the grounds that the subject specification fails to teach a substantial utility for the claimed invention and, therefore, an ordinarily skilled artisan would not know how to use the claimed invention. The Office Action argues that the application has not demonstrated that the claimed polypeptide is associated with prostate cancer. Applicants respectfully assert that the claimed invention has substantial utility and, therefore, is enabled. Applicants note that the as-filed specification discloses that the BAP28 polypeptide has a number of phosphorylation sites and that the claimed polypeptide also contains a motif known to be involved in protein-protein interactions (see page 48, line 33 through to page 49, line 9). As discussed therein, the PCT application WO 98/12327 showed that BAP28 should have the ability to interact with BRCA1 (a known tumor associated antigen). Thus, it is respectfully submitted that one skilled in the art would have recognized that the BAP28 polypeptide of SEQ ID NO: 5 could be used for the detection of BRCA1 in samples. Alternatively, the polypeptide would also have been recognized as being useful as a phosphorylase substrate associated in view of the multitude of phosphorylation sites within the polypeptide. Additionally, the inventors of the present patent application have identified several biallelic markers located within the gene encoding the BAP28 protein that are associated with prostate cancer (see Example 5), and it is respectfully submitted that the ordinarily skilled artisan would have reasonably expected that the BAP28 protein is expressed and associated with prostate cancer. Indeed, the BAP28 polypeptide (also known as HEATR1) is expressed in cells, such as cervical carcinoma cells (HeLa cells; see http://www.expasy.org/swiss-2dpage/protein/ac=Q9H583). Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §§ 101 and 112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made <u>solely</u> to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants

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expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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